

MANUFACTURER'S DECLARATION OF CONFORMITY**AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002****DECLARATION OF CONFORMITY PROCEDURES**

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: Welch Allyn, Inc.
Business address: 4341 State Street Road
 Skaneateles Falls, NY USA 13153-0220
Medical device(s): Illuminator
 REF: 901025 ILLUMINATOR, HAND HELD
 See Appendix 1 for a list
Classification: Class I
GMDN code and term: 36761 Skin Transilluminator
 12276 Light Examination
Scope of application: All
 Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Full quality assurance

procedures certificate: 314505 MP2016

Standards applied:

| Standard | Version | Title |
|------------------|--------------------|--|
| EN ISO/ISO 13485 | 2016 | Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes |
| EN ISO/ISO 14971 | 2012/2ED 2007 | Medical Devices - Application of Risk Management to Medical Devices |
| EN/IEC 60601-1 | 2006/ 2005+A1 | Medical Electrical Equipment - Part 1: General Requirements for Safety |
| EN/IEC 60601-1-2 | 4ED 2014- 02-25 | Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests |
| EN/IEC 60601-1-6 | 2010/3ED 2010 | Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability |
| IEC 60601-1-6 | 2004 | Medical Electrical Equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability |
| EN/IEC 62366 | 2008 | Medical Devices – Application of Usability Engineering to Medical Devices |

Standards applied:

| Standard | Version | Title |
|----------------|---------------------|--|
| EN ISO 10993-1 | 2009 + Corr 2010 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |



Joshua Kim
Senior Manager, Regulatory Affairs

2021.09.22
Date

Appendix 1 –Products

| Part Number | Description | GMDN Code | Used in Sets |
|-------------|---|-----------------------------|--------------|
| 22009 | POLY SPECULUM 9MM | 12267 Light Illumination | NA |
| 23557 | ILLUMIN SECTION ONLY | 12267 Light Illumination | NA |
| 23857 | BBO THROAT ILLUMINATOR FINISHED SET | 12267 Light Illumination | NA |
| 26330 | MAGNIFYING LENS F/26035 | 12267 Light Illumination | NA |
| 26530 | 3.5V HALOGEN NASAL ILLUMINATOR | 12267 Light Illumination | NA |
| 26531 | NASAL ILLULM. ASSEMBLY | 12267 Light Illumination | NA |
| 26535 | NASAL ILLUM SECT ONLY | 12267 Light Illumination | NA |
| 26538 | FBR OPTIC NASAL ILLUMINATOR MACROVIEW | 12267 Light Illumination | NA |
| 26550 | NASAL ILLUMINATOR SECTION ONLY | 12267 Light Illumination | NA |
| 41100 | 3.5V FO FINNOFF TRANSILLUM | 36761 Skin Transilluminator | 18335-SSP5 |
| 41101 | 3.5V FINNOFF TRANSILL W/FILTER | 36761 Skin Transilluminator | NA |
| 41102 | COBALT BLUE FILTER | 36761 Skin Transilluminator | NA |
| 43300 | 3.5V CURVED TRANSILLUMINAT | 36761 Skin Transilluminator | NA |
| 28100 | 3.5V HAL TONGUE BLADE HOLDER | 12267 Light Illumination | NA |